K022075

SEP 1 9 2002

Summary of Safety and Effectiveness

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this is to serve as a Summary of Safety and Effectiveness for the proposed CP Medical CP-WIRE component device.

Manufacturer:

CP Medical, Inc.
2414 NE Pacific Avenue
Portland, OR 97232
PHONE: (503) 232-1555
FAX: (503) 230-9993

Contact Person: Mary Ann Greenawalt, Vice President
Legal & Regulatory Affairs

Device Name:

Trade Name: Disposable Temporary Pacing Cable

Common Name: Component to diagnostic or physiological monitoring devices

Proprietary name: TBD

Classification: Cable, Transducer and Electrode, Patient (including Connector), Cardiovascular, DSA, Class II

Date Prepared: June 25, 2002

Predicate Device: The predicate device is the Remington Medical, Inc. disposable Surgical Cable and the disposable Extension Cable for cardiovascular monitoring application.

Device Description: The CP Medical device consists of 22-gauge metallic wire and safety connectors for cardiovascular monitoring application.

Intended Use: The CP Medical device, disposable temporary pacing cable, is intended to be used as an interface between various diagnostic and physiological monitoring devices (not manufactured by CP Medical) and disposable sensor devices (not manufactured by CP Medical) which are attached to a patient body. CP Medical disposable temporary pacing cable is limited by the Indications for Use of the connected diagnostic or physiological Monitoring Device.

Indications: CP Medical's Disposable Temporary Pacing Cable with safety connectors is indicated for use as an electrical extension cable used to transmit signal from, or

power or excitation signal to patient-connected electrodes. The cable is bipolar, providing alligator clips at the end of the cable that will be attached to the patient's lead, and a safety plug at the other end that allows electrical connection to the external pacemaker or testing device (i.e., analyzer). The alligator clips are color-coded and imprinted with the polarity: The red clips are positive (+) and the black clips are negative (-).

The cable is designed to carry a maximum electrical load of 300 volts, and will be compatible with most external pacemakers, pace analyzers, and patient pacing leads currently on the market.

The cable is a sterile (or OEM non-sterile), disposable device.

Comparison of Technological Characteristics: The proposed device, the disposable temporary pacing cable, is comprised of the same or similar material as the predicate device. Manufacture of this device, and QC testing, will be in substantial compliance with current ANSI/AAMI EC53:1995, EC53:1998 amendment, IEC 60601 subclause 56.3 and 21CFR 820 (QSR).

end

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2002

CP Medical, Inc.
c/o Ms. Mary Ann Greenawalt
Director, Regulatory and Quality
836 NE 24th Avenue
Portland, OR 97232

Re: K022075
Trade Name: Disposable Temporary Pacing Cable
Regulation Number: 21 CFR 870.2900
Regulation Name: Cable, Transducer and Electrode, Patient
Regulatory Class: Class II (two)
Product Code: DSA
Dated: June 25, 2002
Received: June 26, 2002

Dear Ms. Greenawalt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) (if known): K022075

DEVICE Name: Disposable Temporary Pacing Cable

Indications for Use:

CP Medical's Disposable Temporary Pacing Cable with safety connectors is indicated for use as an electrical extension cable used to transmit signal from, or power or excitation signal to, patient-connected electrodes. The cable is bipolar, providing alligator clips at the end of the cable that will be attached to the patient's lead, and a safety plug at the other end that allows electrical connection to the external pacemaker or testing device, i.e., analyzer. The alligator clips are color-coded and imprinted with the polarity: The red clips are positive (+) and the black clips are negative (-).

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____

Division of Cardiovascular & Respiratory Devices
510(k) Number K022075